DEPARTMENT OF HEALTH & HUMAN SERVICES 91808d

Food & Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-85

September 24, 2001

Mr. Cesar Vasquez
President/Owner
AMA Therapeutics, Inc.
d/b/a A.M.A. Pharmaceuticals
2818 NW 79th Ave
Miami, FL 33122-1033

Dear Mr. Vasquez,

On February 1, 2001, the U.S. Food and Drug Administration inspected a shipment of prescription drug products offered for imported into the United States by your firm as invoiced on January 8, 2001, under airway bill number [redacted]. The referenced shipment contained the following prescription drug products:

DOBUTAMINE HYDROCHLORIDE
Proprietary Name DOBUTAMINE HCL Applicant: BEDFORD
Strength: EQ 12.5MG BASE/ML
[redacted] Reference Listed Drug: No RX/OTC/DISCN: RX

CYTARABINE
Applicant: BEDFORD
Strength: 100MG/VIAL [redacted] Reference Listed Drug: No RX/OTC/DISCN: RX

ALPROSTADIL
Applicant: BEDFORD Strength: 0.5MG/ML [redacted] Reference Listed Drug: No
RX/OTC/DISCN: RX

These products are manufactured by Ben Venue Laboratories, Inc. located in Bedford, Ohio and for Bedford Laboratories, Bedford, Ohio. Further review identified that the referenced shipment was offered as an FDA disclaim to U.S. Customs upon entry, even though these products are clearly regulated by the U.S. Food and Drug Administration. The information on the CF 3461 identified the Consignee and Importer of Record as [redacted]

The importation of a prescription drug originally manufactured in the United States to anyone other than the manufacturer, except in the case of a documented medical emergency, is a violation of section 203.10 of the Code of Federal Regulations (21 CFR 203.10), and sections 331(t) and 381(d)(1) of Title 21 of the U. S. Code [21 U.S.C. 311(t) and 21 U.S.C. 381(d)(1)]. Other provisions of law may also be violated, such as 19 U.S.C. 1592 and 108 U.S.C. 542.

For your information, violations of 21 U.S.C. 331(t)/381(d)(1) are punishable with imprisonment for up to 10 years and a fine not more than $250,000.00 or both.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation.

Your written reply should be addressed to the Food and Drug Administration, Attention: Christine M. Humphrey, Compliance Officer, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Emma R. Singleton
Director, Florida District

cc: Hellman Worldwide Logistics
10450 Doral Blvd.
Miami, FL 33178

Ben Venue Laboratories
300 Northfield Rd.
Bedford, OH 44146-4650